REMARKS

Claims 68-127 and 129-137 are pending in the subject application. Claims 68, 74, 79, 83, 93, 97, 99, 108, 111, 116, 129 are amended herein, claims 121, 130, and 131 are canceled, without prejudice, and claim 138 is added. Applicants submit that the amendments herein introduce no new matter, support therefore being found throughout the application and drawings as originally filed. Favorable reconsideration in light of the amendments and remarks which follow is respectfully requested.

1. Oath/Declaration

The Examiner has requested a new oath or declaration, because currently it does not state that the person making the oath or declaration acknowledges the duty to disclose to the Office all information known to the person to be material to patentability as defined in 37 CFR 1.56. Applicants will submit the new declaration to the Patent Office in due course.

2. Specification

The Office asserts that "[t]he specification fails to disclose the cap element being sized to provide a cross-section larger than the cross-section area of the coil or the zig-zag shape or the cross-section of the coil-shaped member" "the cap element being sized to prevent the cap element from passing through an incision where the cap element mates against the patient eye outer surface" and "the body member being in contact with intravitreal fluid." Applicants respectfully traverse this objection.

With respect to the cap element being sized to provide a cross-section larger than the cross-section of the coil or zig-zag shape or the cross-section of the coil-shaped member, Applicants respectfully submit that Figs. 1a, 2a, 3a-c, and 5a-b clearly show the cap element 8 sized larger than the cross-section of the coil or zig-zag shape or the cross-section of the coil-shaped member 2. Reconsideration and withdrawal of the rejection is respectfully requested.

With respect to the cap element being sized to prevent the cap element from passing through an incision, Applicants respectfully submit that paragraph [0045] discloses this. Paragraph [0045] of U.S. Publication No. 2004/0133155 reads as follows, with emphasis added:

> The overall size and shape of the rim or cap 8 is not particularly limited provided that irritation to the eye is limited. For example, while the rim or cap 8 is shown circular in shape, the rim or cap may be of any shape, for example, circular, rectangular, triangular, etc. However, to minimize irritation to the eye, the rim or cap 8 preferably has rounded edges. Further, the rim or cap 8 is designed such that it remains outside the eye and, as such, the rim or cap 8 is sized so that it will not pass into the eye through the opening in the eye through which the device is inserted. The rim or cap 8 may further be designed such that it can be easily sutured or otherwise secured to the surface surrounding the opening in the eye and may, for example, contain a plurality of holes (not shown) through which sutures may pass.

Reconsideration and withdrawal of the rejection is respectfully requested.

With respect to the cap element mating against the patient eye outer surface, without agreeing with the rejection, Applicants have amended claim 74 to recite that the cap element is in contact with the patient eye outer surface. As set out, the device is inserted into the eye with the rim or cap remaining outside of the eye until the rim or cap abuts the incision [0044], and the rim or cap is fabricated of a material that does not cause irritation to the portion of the eye that it contacts [0046]. Thus, Applicants respectfully submit that there is support for a cap element being in contact with the patient eye outer surface.

With respect to the body member being in contact with intravitreal fluid, Applicants respectfully submit that Fig. 1A clearly shows the body member being in contact with intravitreal fluid (also referred to as vitreous humor). The intravitreal fluid/vitreous humor is the gelatinous substance that fills the chamber of the eye between the retina and the lens, and the body member is shown positioned in this chamber. As further set out by Applicants, the non-linear or coil-shaped geometry of the body provides a "large intravitreal surface area" (paragraph [0036]-[0037]). Clearly, the body member, which is shown inserted inside of the vitreous humor

(Fig. 1A) and which is described as having a large intravitreal surface area, contacts intravitreal fluid. Reconsideration and withdrawal of the rejection is respectfully requested.

3. Claim Objections

Claims 108 and 130 have been objected to. Applicants have amended the claims as requested by the Office.

4. 35 U.S.C. §112 Rejections

Claims 108 and 130 are rejected under 35 U.S.C. §112, first and second paragraphs. Applicants have amended claims 108 and 130 as requested. Applicants respectfully request reconsideration and withdrawal of the rejection.

5. 35 U.S.C. §102 Rejections

Rosenman et al.

Claims 83-91 are rejected under 35 U.S.C. §102(e) over U.S. Patent No. 6,478,776 to Rosenman et al. ("Rosenman"). Applicants respectfully traverse.

Rosenman at least does not teach or suggest a method for treating a patient by inserting into a patient's eye a delivery device comprising a non-linear shaped body member that has a coil or zig-zag shape and a cap element, wherein the cap element sized to provide a cross-section larger than the cross-section of the coil or zig-zag shape, and wherein the device is inserted with the cap element remaining outside the incision and abuts the outer surface of the eye to stabilize the device, as recited in amended claim 83.

Rather, Rosenman describes methods wherein a device is implanted in the myocardium. Further, while Rosenman's device has a cap element (56), it is not sized to provide a cross-section larger than the cross-section of Rosenman's helix 12. Further, Rosenman describes methods wherein a device is implanted in the myocardium such that it is disposed completely within the myocardium, with the proximal tip of the device being below the level of the endocardium. (see Rosenman, col. 11, ll. 50-53). According to Rosenman, this is a required

feature to prevent therapeutic agents such as drug particles or growth factors from being released into the ventricle of the heart and from there into the systemic arterial circulation, causing unwanted and potentially dangerous effects such as tissue ischemia and embolic events (see Rosenman, col. 3, ll. 51-64). Thus, Rosenman does not teach or suggest methods wherein the device is inserted with the cap element remaining outside the incision and abuting the outer surface to stabilize the device.

With respect to the Office's assertion that Rosenman's "cap element would be seen to remain outside of and abut the incision as the device of Figure 19 is being inserted through the incision", Applicants respectfully disagree. Figure 19 merely shows Rosenman's device in isolation and does not at all depict the bodily structure in which the device is inserted. Nowhere in Rosenman's specification or in the Figures is it ever taught or even suggested that Rosenman's device is inserted with any portion of the device remaining outside of the the myocardium. Rather, Rosenman teaches that the entire device is inserted completely within the myocardium.

Thus, it is respectfully submitted that claim 83 is patentable over Rosenman. Claims 84-91 depend from claim 83, and, thus, also are patentable over Rosenman. Reconsideration and withdrawal of the rejections is respectfully requested.

Altman

Claims 83-91 are rejected under 35 U.S.C. §102(b) over U.S. Patent No. 5,551,427 to Altman ("Altman"). Applicants respectfully traverse.

Altman at least fails to teach or suggest a method for treating a patient by inserting into a patient's eye a delivery device comprising a non-linear shaped body member that has a coil or zig-zag shape and a cap element. Altman, like Rosenman, describes an implantable device that is implanted into the cardiac tissue to treat cardiac arrhythmia.

Accordingly, Applicants submit that claim 83 is patentable over Altman. Claims 84-91 depend from claim 83 and, thus, also are patentable over Altman. Reconsideration and withdrawal of the rejections is respectfully requested.

6. 35 U.S.C.§103 Rejections

Weiner et al. and Darougar et al.

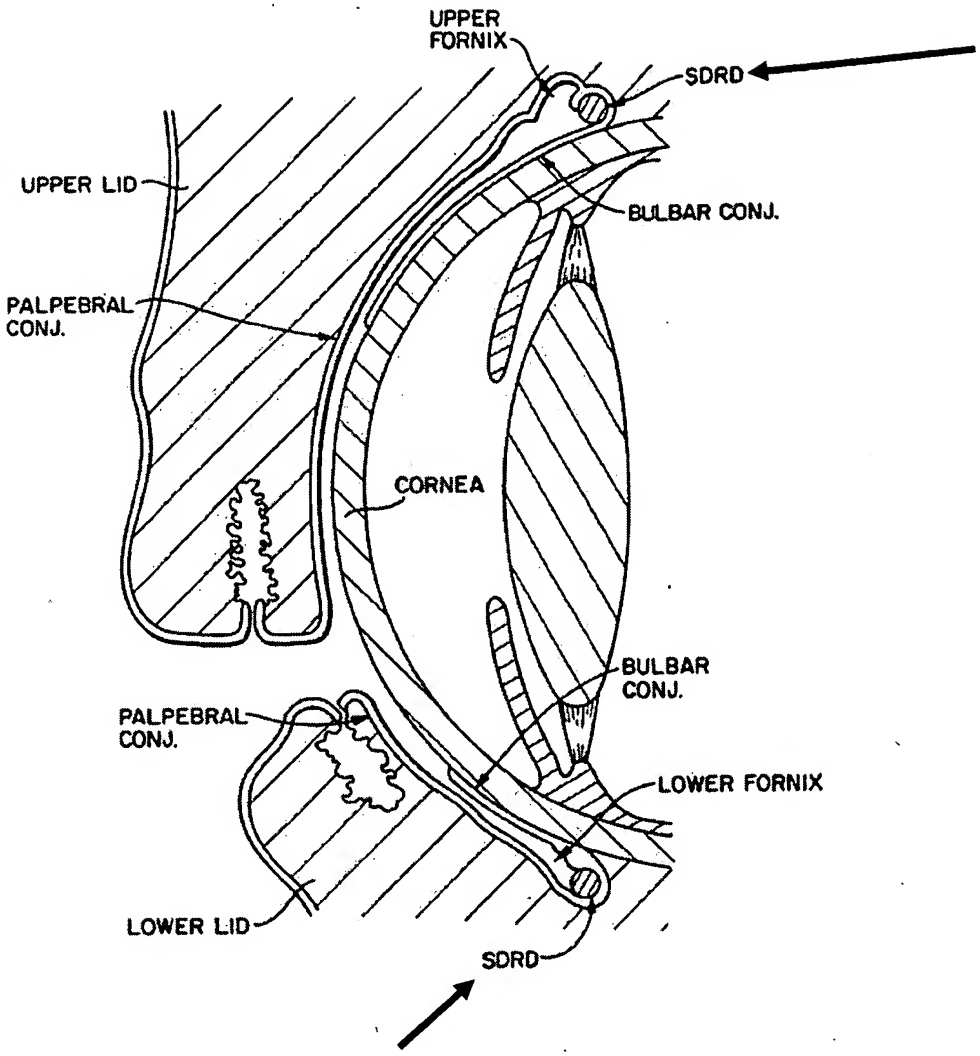
Claims 68-91, 93-97, 99-109, 111-127, and 129-137 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,466,233 to Weiner et al. ("Weiner") and U.S. Patent No. 5,395,618 to Darougar et al.("Darougar"). Applicants respectfully traverse.

Weiner describes a tack 10 for drug delivery. The tack 10 comprises a post 12, a central portion 14, and a head 16. In one embodiment, the central portion 14 is provided as an anchoring region 14a for securing the tack within the eye, and in another embodiment As set out, the central portion may have an anchoring region 14a for securing the tack 10 within the eye (see, e.g. col. 4, lines 40-44). In particular, the anchoring region 14a is provided with a minimum width g and a maximum width f, such that a first and second portion 36, 38 are formed which appear concave (or convex) (see, e.g. col. 5, lines 51-66). In particular, according to Weiner, an anchoring region 14a is provided to secure the tack by anchoring the central portion 14 to the retina, choroids, and/or the sclera (see col. 6, lines 1-11).

As set forth above, and as acknowledged by the Office on page 11 of the Office action, Weiner does not teach or suggest delivery devices comprising a coil or zig-zag shaped body member or methods of using such a coil or zig-zag shaped body member. However, the Office points to Darougar, which the Office asserts "discloses an implantable drug delivery device" which comprises a "helical shape or a substantially Z-shape", pointing to Figs. 8 and 12.

Applicants respectfully submit that Darougar does not teach or suggest an implantable drug delivery device or methods of use wherein the device comprises a body member having a helical shape or a substantially zig-zag shape in accordance with Applicants' claims. For example, Darougar does not teach or suggest a tube provided or wound into a coul or zig-zag

shape wherein the device is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member, as recited in Applicants' amended independent claims 68, 79, 83, 111, or 129. Darougar also does not teach or suggest a device or method wherein the device is insertable through an incision smaller than the cross-section of the body member, as recited in amended independent claims 93, 99, and 116. Darougar describes an ocular device that is provided in the upper or lower fornix of the conjunctiva between the sclera of the eyeball and the upper or lower eyelid. The pressure of the lid against the eyeball helps to hold the device in place under the eyelid (see col. 3, lines 19-61). The device is shown inserted in Figs. 4-6 and is identified as **SDRD** (col. 9, lines 56-59). Clearly, as depicted in Fig. 4 reproduced below, the device (**SDRD**) is positioned exterior the eyeball and is not an implantable device inserted within the eye:



Thus, Darougar's devices are not insertion devices inserted in an eye – they are positioned between the outer surface of the eye and the eye lid. Further, in none of Darougar's embodiments is a coil or zig-zag shaped body member provided in the form of a tube in a coil or zig-zag shape such that the device is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member. Further none of the devices of Darougar would be insertable through an incision smaller than the cross-section of the body member.

Thus, Applicants respectfully submit that Weiner and Darougar teach two different types of devices that are used in completely different ways. Weiner's tack is inserted into the eye (so as to pierce the eye and resides inside of the eye). Darougar's device is positioned exterior the eye between the outer surface of the eye and the eye lid. It is submitted that one would not modify Weiner's device, which pierces the eye and resides inside of the eye, with Darougar's device, which doesn't enter the eye at all but, rather, is positioned along the outer surface of the eyeball. Such different positioning of the devices of Weiner and Darougar would necessarily call for distinct device geometires and characteristics. Applicants note that the Office asserts that "Darougar et al disclose that it is well known to provide an implantable device with a coil or zig-zag shape so that the device can be propely positioned and maintained in the desired location in a patient's body". However, Darougar's device is designed to be maintained along a curved outer surface of the eye. One looking to maintain or anchor Weiner's tack - which is inserted inside of the eye and which Weiner teaches is anchored using an anchoring region 14a - would not look to Darougar's externally positioned device.

It is further respectfully submitted that even in Weiner and Darougar were combined, Applicants' device and methods still would not be taught or suggested. In particular, neither Weiner nor Darougar teach or suggest a device that is implantable through an incision smaller than the cross-section of the body member or a device having a coil or zig-zag shaped body member provided in the form of a tube in a coil or zig-zag shape such that the device is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member.

In view thereof, it is respectfully submitted that claims 68, 79, 83, 93, 99, 111, 116, and 129 are patentable over Weiner and Darougar. Claims 69-78, 80-82, 84-92, 94-98, 100-109, 112-127, and 130-138 depend from claims 68, 79, 83, 93, 99, 111, 116, and 129, and, thus, also are patentable over Weiner and Darougar. Reconsideration and withdrawal of the rejections is respectfully requested.

Rosenman et al. and Johnson

Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al. and U.S. Patent No. 5,972,027 to Johnson ("Johnson").

As set forth above, Rosenman describes methods wherein a device is implanted in the myocardium, and wherein the device is implanted in the myocardium such that it is disposed completely within the myocardium, with the proximal tip of the device being below the level of the endocardium. Further, while Rosenman's cap element (56), it is not sized to provide a cross-section larger than the cross-section of Rosenman's helix 12.

Johnson is cited for describing shape memory materials. However, Johnson does not remedy the above-noted deficiencies in Rosenman.

Accordingly, claim 83 is patentable over Rosenma and Johnson. Claim 92 depends from claim 83, and, thus, also is patentable over Rosenman and Johnson. Reconsideration and withdrawal of the rejections is respectfully requested.

Weiner et al., Darougar et al., and Johnson

Claims 92, 98, and 110 are rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner, Darougar, and Johnson.

As set forth above, when the entire Weiner and Darougar references are read in their entirety, one of skill in the art would not have modified Weiner in view of Darougar as proposed in the Office action. Further, even in Weiner and Darougar were combined, Applicants' device and methods still would not be taught or suggested. In particular, neither Weiner nor Darougar teach or suggest a device that is implantable through an incision smaller than the cross-section of the body member or a device having a coil or zig-zag shaped body member provided in the form of a tube in a coil or zig-zag shape such that the device is insertable through an incision approximately the same size as the outer diameter of the tube forming the body member.

Further, Johnson, which is cited for describing shape memory materials, does not remedy the above-noted deficiencies in Weiner and Darougar.

In view thereof, it is respectfully submitted that claims 83, 93, and 99 are patentable over Weiner, Darougar, and Johnson. Claims 92, 98, and 110 depend from claims 83, 93, and 99, and, thus, also are patentable over Weiner, Darougar, and Johnson. Reconsideration and withdrawal of the rejections is respectfully requested.

Weiner et al. and Johnson

Claim 110 is rejected under 35 U.S.C. 103(a) as being unpatentable over Weiner and Johnson. Applicants respectfully traverse.

As set forth above, Weiner at least does not teach or suggest an implant or methods for inserting an implant comprising a coil or zig-zag shaped body member, wherein the implant is inserted through an incision smaller than the cross-section of the coil or zig-zag shaped body member.

In view thereof, it is respectfully submitted that claims 68, 79, 83, 93, 99, 111, 116, and 129 are patentable over Weiner and Johnson. Claims 69-78, 80-82, 84-92, 94-98, 100-110, 112-115, 117-127, and 130-137 depend from claims 68, 79, 83, 93, 99, 111, 116, and 129, and, thus, also are patentable over Weiner and Johnson. Reconsideration and withdrawal of the rejections is respectfully requested.

CONCLUSION

It is respectfully submitted that the subject application is in a condition for allowance. Early and favorable action is requested.

If for any reason the fee paid is inadequate or credit is owed for any excess fee paid, the Office is hereby authorized and requested to charge Deposit Account No. **04-1105**.

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Respectfully submitted,
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